

Do Respirators Protect Health-Care Workers From Airborne Infectious Diseases?

The burdensome nature of wearing a respirator has driven controversy on the effectiveness of respiratory protection for health-care workers for many years. The safety and industrial hygiene communities have insisted on appropriate, dutiful, compulsive practice that includes fit testing. Legislative amendments have blocked elements such as fit testing. Most importantly, health-care workers have pushed back, requesting standards of evidence common in the clinical practice of medicine but almost unheard of in environmental science. The question has been posed: do respirators protect health-care workers from airborne infectious diseases? In fact, it appears that the correct answer is, “no one knows.”

Before the 1990s and the resurgence of tuberculosis (TB) worldwide and in the United States, respirator use among health-care workers was rare. In 1994 the Centers for Disease Control and Prevention issued guidelines that called for respirator use among health-care workers caring for TB patients. The Occupational Safety and Health Administration (OSHA) promoted stronger language that supported enforcement of its respiratory protection standard (Code of Federal Regulations 29 Part 1910.134) as part of TB-control policies and programs. This standard required respirators “in environments where occupational transmission of TB is possible.” Studies that showed that health-care workers were increasingly becoming exposed to, and in some cases contracting, TB in the workplace forced these changes.¹⁻⁹ The demand for action was never greater than during the period when numerous health-care workers became infected with multiple-drug-resistant TB, and several died.¹⁰⁻¹⁵

Unfortunately, there have been no well-designed clinical trials to determine which types of respirators actually prevent airborne occupational illness. Such studies, which typically require many years, were viewed as far too time-consuming, because urgent action was necessary to prevent health-care-associated TB, so the Centers for Disease Control and Prevention recommended broad-based implementation of 3 key infection-control measures: administrative controls, engineering controls, and personal respiratory protective equipment.¹⁶ Several studies found that implementation of this wide-ranging TB-control program decreased the incidence of positive tuberculin skin tests among employees.¹⁷⁻²⁰ In fact, TB all but disappeared as a

health-care-associated infection. Some evidence suggests that the majority of subsequent outbreaks were related more to poor clinical practice (ie, failure to identify active TB cases in the hospital) than to inadequate respiratory-isolation programs.²¹ Although the conversion rate decreased, it was not known which measure(s) contributed to the decline; it was known only that the 3 measures worked together. The available evidence did not weigh in support of respirators. In fact, the Institute of Medicine concluded that “personal respirators did not appear to play a significant role in ending outbreaks of TB.”²² A lack of clinical trial data and other limitations have led some to argue that the enforcement of OSHA’s respiratory protection standard was not supported by sufficient evidence, and less rigid measures should be utilized.^{22,23}

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Still, respirators have played an increasing role in personal protection for health-care workers. The Centers for Disease Control and Prevention now recommends the use of N95 respirators by workers who may be exposed to anthrax, monkeypox, severe acute respiratory syndrome (SARS), smallpox, or viral hemorrhagic fevers.²⁴ Similarly, consideration has been given to the use of N95s to prevent the transmission of measles, varicella, and influenza to health-care workers.²⁴

A substantial body of laboratory evidence supports OSHA’s requirements. For instance, one field of research examines respirator performance by measuring the ratio of airborne contaminant concentrations between the interior and exterior of the respirator. These laboratory studies use ambient or created non-toxic particles to estimate the expected protection from hazardous airborne contaminants. Depending on the study design (in vivo or in situ), such a study produces an estimated level of protection, called a “simulated workplace protection factor.” The modifier “simulated” prefaces the term “protection factor” because these studies are conducted under controlled conditions that may not adequately predict performance under actual workplace conditions. Despite its limitations, this type of study is an important basis for understanding the interaction between humans and respirators, and provides a foun-

dation for understanding and designing respirators used in the workplace, and for occupational policy and regulation.

Though laboratory studies have been immensely helpful, they are often limited by their practical applicability. For example, a simulated-workplace-protection-factor study often is conducted with the wearer standing, sitting, talking, turning her head, or bending forward. This type of test is done in lieu of a clinical study that compares the difference in occurrence of a disease (such as TB) among health-care workers who are equipped with a respirator versus other protective measures. There are numerous barriers to conducting an ideal clinical study; therefore, a laboratory study is done instead. In this context, the laboratory serves as a surrogate for the patient's room, inert particles serve as a surrogate for *Mycobacterium tuberculosis*, and various exercises, such as talking or bending forward, serve as surrogates for occupational activities. In addition, the existence of inert particles in the interior of the respirator serves as a surrogate for TB exposure, which, in turn, serves as a surrogate for the likelihood of becoming infected with TB. The vast majority of respirator studies are done in this type of laboratory environment. These studies often do not assess workplace environmental issues, such as the difficulties workers may have in using such devices, or whether during actual use the respirator is properly fit, functioning, and used as directed. Rarely are studies done with health-care workers actually performing their occupational duties; this limits such studies' generalizability. In addition, the airborne concentration of infectious agents is often so low that meaningful analysis can be difficult.²⁵

In this issue of *RESPIRATORY CARE*, Roberge et al²⁶ describe efforts to evaluate respirator effectiveness in a laboratory environment designed to simulate the health-care workplace. They studied whether wearing an N95 respirator with a powered air-purifying respirator (PAPR) enhanced the protection, compared to N95 or PAPR alone. Simultaneous use of an N95 and a PAPR, although not practiced widely, has been used by some health-care workers seeking extra respiratory protection (eg, during the SARS epidemic). Though it is intuitive that wearing 2 respirators instead of one would provide better protection, there have been no data to support this notion, until Roberge and colleagues completed their study.²⁶ A major limitation of the study, which the authors clearly identify, was the need to glue the N95 respirator to the mannequin's face to determine a simulated protection factor. Clearly, it would not be possible to glue the mask to the health-care worker's face because of the risk of facial or skin irritation or injury, so the data from Roberge et al²⁶ give an inaccurate indication of the actual in situ protection. A more common approach than the use of a mannequin is to have human subjects wear respirators while exposed to a harmless airborne contaminant. The Roberge et al study²⁶ mea-

sured the efficacy of the N95 filter media, as opposed to measuring contaminant penetration through the filter media *and* around the edge where the respirator meets the face. It is generally accepted that most of the contaminants measured inside an N95 respirator are from mask-edge leakage, not penetration through the filter media. This is an example of the limitations of laboratory research that dramatically limit its real-world applicability. The indirect evidence it generates is only a surrogate for clinical trial data. The laboratory is an appropriate place to start studying an idea, but the data should be validated in a clinical setting.

Some of the challenges of clinical studies are unique to health care. For chemical (eg, lead, asbestos, silica) and physical hazards (eg, noise, ionizing radiation) there are both exposure limits and methods to quantitatively monitor the hazard. Once this information is known, a respirator can be chosen based on protection factor (the minimum ratio of the outside vs inside concentration expected while wearing a specific respirator) and other factors (eg, the ability of the filter or sorbent to remove the contaminant). For infectious agents there are generally no exposure limits. In fact, the infectious dose for humans is often unknown. Even accurately monitoring the airborne exposure level is typically difficult. This creates uncertainty in the proper selection of a respirator. Studying the incidence of infection among health-care workers exposed to infectious diseases during work may be the only method, really, to justify the choice of a specific respirator for protecting health-care workers. Although this approach might be considered unethical in certain circumstances, preparing for and implementing this type of study as opportunistic research during a pandemic may be necessary.

The time has come to invest sufficient resources to determine how well respirators work in the clinical setting. With recent emphasis on public health preparedness for an influenza pandemic, bioterrorism, SARS, and other respiratory infectious diseases, respirators and respiratory-protection programs have become more widely used and stand to become a fixture in infection control. France recently decided to purchase 685 million respirators for use during an influenza pandemic.²⁷ 3M sought Food and Drug Administration approval to market its 8612F and 8670F N95 respirators to the general public for use during a public health crisis such as an influenza pandemic.²⁸ Before traveling any farther down this pathway, the health care and public health communities need to know if these respirators really protect against routine exposure to airborne infectious agents or are adequate for high-risk procedures. We should begin conducting well-designed clinical trials without further delay. There are several key reasons why.

First, if common sense is *correct* about respirator effectiveness, then we need to amass sufficient evidence to convince health-care workers and health systems to com-

ply with personal-protective-equipment guidelines and standards. Health-care-worker use of N95s or surgical masks has been below 60% in many clinical settings.²⁹⁻³⁴ Doctors are often the least likely clinicians to follow the guidelines. One reason clinicians cite is the belief that the recommended respiratory protection is ineffective or not necessary.²⁹⁻³¹ To get health-care workers to wear something uncomfortable that they perceive interferes with occupational activities, they need to be convinced that it is a necessary protective measure. The same might be said for the fit-testing component of respiratory protection programs. If definitive clinical evidence emerges and is combined with laboratory data³⁵ that show that health-care workers are more likely to become ill if they do not undergo fit-testing, there might be less resistance to, or even a preference for, fit-testing.

Second, if common sense is *incorrect* and respirators in fact do little or nothing to protect health-care workers from airborne infections, then we are wasting time, effort, and money. It has been estimated that a hospital should expect to spend \$86,560–\$175,690 annually on its respiratory-protection program.³⁶ In a 1994 analysis, University of Virginia researchers estimated that the various components of health-care worker respiratory protection would cost about \$1.3–18.5 million to prevent one case of occupational TB.³⁷

Third, we must consider the possibility that respirators could actually be causing harm to health-care workers or patients. It is hard to imagine that a respirator might directly hurt someone; the OSHA-mandated medical-approval process should see that each worker is safely equipped. However, the possibility of *indirect* harm should be taken into careful consideration. It is possible that respirator interference with visibility or range of motion might increase the risk of sharps injuries.³⁸ The effects of a respirator on a pregnant health-care worker and her fetus are largely unknown. Communication interference by a respirator could lead to medical errors. Respirators could actually be a source of occupational illness if they are mishandled or inadequately cleaned, disinfected, or discarded. There is also a risk of providing a false sense of security to health-care workers. History tells us that common sense is not always right. Beta carotene was thought to protect against lung cancer until a clinical trial suggested it might actually be a risk factor.³⁹ Hormone replacement was viewed as cardioprotective until data from the Women's Health Initiative revealed it to be a risk factor.⁴⁰

Fourth, failure to answer questions about clinical effectiveness may lead to incorrect decisions or indecision. If health-care leaders don't understand the clinical utility of respirators, they may neglect to direct the donning of equipment when it is essential or be silent when direction is deeply needed. One of the biggest complaints of Toronto's health-care workers during the 2003 SARS crisis was a

lack of clear directives from their public health leaders. This led to confusion, frustration, and possibly preventable illness. More recently, the emphasis has switched from SARS to influenza pandemic preparedness. Concerns have been widespread about the possibility of respirator shortages and whether N95 respirators are superior to surgical masks when caring for influenza pandemic victims. Remarkably, concerns about mask shortage and effectiveness were raised in 1918. An organized labor union representative said, "It is no time to quibble over the worth of the mask. It is the best thing we have found to date, and if you have anything better, for God's sake, give it to us."⁴¹ If we do not step forward proactively, we may be in danger of experiencing the next pandemic without knowing "the worth of the mask."

Finally, to the extent possible, clinical trials on respirator effectiveness need to be done while clinical equipoise exists about their utility. Once respirator use becomes the standard of care for a given disease, as occurred with TB, it becomes no longer ethical to undertake head-to-head comparison trials, which arguably produce the most sound and useful information. At this juncture, in 2008, in part because of increasing concerns about the threat of an influenza pandemic, the medical and public health communities are debating whether respirators or surgical masks should be used to protect health-care workers against influenza. The mode(s) of human-to-human transmission is/are not understood, and the data suggest that influenza might be spread via contact, droplet, aerosol, or some combination of the three.

There is some question whether surgical masks offer health-care workers sufficient protection, especially if influenza (or other infectious agents) is spread via large droplets, and not smaller airborne particulates (often called droplet nuclei). Compared to an N95 respirator, a surgical mask is less expensive, less cumbersome to wear, does not require fit testing, and can be worn over facial hair (eg, beard, moustache, long sideburn). However, the lack of knowledge regarding the comparative performance of masks and respirators should prohibit the selection of masks for airborne infections until clinical data are available. Likewise, there are no clinically derived data that compare the performance of PAPRs to N95 respirators, to determine which device should be chosen during high-risk situations and procedures (eg, bronchoscopy).

A head-to-head comparison of surgical masks to respirators is not appropriate for every disease. It would be unethical to tolerate any risk of exposure to some diseases, such as smallpox or Ebola virus, because of the potential consequences. In that setting a higher-than-usual level of protection becomes the standard of care, even if little or no evidence suggests airborne transmission. But this shouldn't dissuade clinical investigators from a reasoned assessment of trials that may be conducted with the highest ethical

ideals. There are many examples of successful and sound clinical studies that occurred in the context of controversial, if evidence-based, standards of care. High-dose steroids became the standard of care for acute respiratory distress syndrome before there was compelling evidence, and then a series of clinical trials proved them ineffective for acute respiratory distress syndrome.⁴² Larger-than-conventional tidal volumes were thought by some to be at least as effective as conventional mechanical ventilation for acute respiratory distress syndrome until it was shown that low tidal volumes decreased mortality.⁴³ These types of trials require careful, reasoned planning and close scrutiny by data safety monitoring boards, but often they can be done with a sufficient investment of resources.

In conclusion, we wish to reiterate that laboratory investigations should not be discounted. They form the foundation of respirator knowledge. In an era of evidence-based medicine, decisive clinical trials hold an important place in product development. During the pharmaceutical development process, a new drug's effectiveness is tested in laboratory and clinical trials before a request is made to the Food and Drug Administration for approval to market.⁴⁴ Similarly, where feasible and ethical, prospective clinical trials should be a component of respirator development. We need to know if respirators protect health-care workers from airborne infectious diseases. If respirators don't work in certain circumstances, despite an intuition that suggests they should, we need to stop using them, because we might be causing harm, if not directly, then perhaps indirectly. We don't want to face another influenza pandemic where we "quibble over the worth of the mask."

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